PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
SQUIRE, SANDERS & DEMPSEY L.L.P.
Attn. Lupkowski, Mark
One Maritime Plaza, Suite 300
San Francisco, CA 94111-3492
ETATS-UNIS D'AMERIQUE

DOCKETED: Art. 19 Amendment due 1/9/07
File IDS in .34 by 2/9/07

NOV 17 2006

BY FB Atty: ML
SQUIRE, SANDERS & DEMPSEY

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 62571.00141	Date of mailing (day/month/year) 09/11/2006
International application No. PCT/US2006/025937	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant ADVANCED CARDIOVASCULAR SYSTEMS, INC.	International filing date (day/month/year) 30/06/2006

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
   1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within 19 **months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 **months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase betore those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Tx. 31 651 epo nl	Dominique Hundt

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims,description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
62571.00141		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2006/025937	30/06/2006	30/06/2005

Applicant

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] ~~**Certain claims were found unsearchable** (See Box No. II)~~

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 7
      [X] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

INTE. .ATIONAL SEARCH REPORT

International application No
PCT/US2006/025937

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L31/14 A61F2/82

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61L A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	WO 98/56312 A (SCIMED LIFE SYSTEMS INC [US]) 17 December 1998 (1998-12-17) claims 1-4,14 page 2, lines 20-24 page 2, line 28 - page 3, line 3 page 3, lines 13-19 page 6, line 7 - page 7, line 5	1-3, 26-29
Y		4-25, 30-32
X,Y	US 2003/153972 A1 (HELMUS MICHAEL [US]) 14 August 2003 (2003-08-14) paragraphs [0009], [0013], [0016], [0036] - [0038], [0046], [0047], [0057], [0069], [0070]	1-3, 26-29
Y		4-25, 30-32

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 2006	09/11/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,	Ponis Antoli Ponto

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 362 603 A2 (TERUMO CORP [JP]) 19 November 2003 (2003-11-19) claims 1,3,7-11 paragraphs [0028], [0031], [0032]	4,6,10
Y	paragraphs [0066] - [0071]	4-25
Y	US 6 867 248 B1 (MARTIN DAVID P [US] ET AL) 15 March 2005 (2005-03-15) column 4, lines 6-26 column 9, lines 23-35 column 9, line 56 - column 10, line 15 column 14, lines 29-33	1-32
Y	US 5 624 411 A (TUCH RONALD J [US]) 29 April 1997 (1997-04-29) claims 1,3-5,19-23 column 3, lines 15,16,27-34 column 7, lines 5-15,27-61	4-25
Y	US 2004/034409 A1 (HEUBLEIN BERND [DE] ET AL) 19 February 2004 (2004-02-19) claims 1-8	6,7,16, 22,32
Y	DE 103 57 747 A1 (MNEMOSCIENCE GMBH [DE]) 5 January 2005 (2005-01-05) claims 1-3,6	6,7,16, 22,32
Y	US 5 916 584 A (O'DONOGHUE MICHAEL F [AU] ET AL) 29 June 1999 (1999-06-29) column 3, lines 39-48 column 7, line 51 - column 8, line 61	30-32
Y	US 5 518 730 A (FUISZ RICHARD C [US]) 21 May 1996 (1996-05-21) column 2, line 64 - column 4, line 12	30-32
A	US 2002/165601 A1 (CLERC CLAUDE O [US]) 7 November 2002 (2002-11-07) claims 1-13	1-32

INTE. ATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/025937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9856312 A	17-12-1998	NONE	
US 2003153972 A1	14-08-2003	AU 2003215224 A1	04-09-2003
		EP 1492580 A1	05-01-2005
		WO 03068288 A1	21-08-2003
EP 1362603 A2	19-11-2003	AT 318623 T	15-03-2006
		DE 60303705 T2	19-10-2006
		US 2003216806 A1	20-11-2003
US 6867248 B1	15-03-2005	US 2003236320 A1	25-12-2003
US 5624411 A	29-04-1997	DE 69431457 D1	07-11-2002
		DE 69431457 T2	26-06-2003
		EP 0623354 A1	09-11-1994
		JP 3673973 B2	20-07-2005
		JP 8033718 A	06-02-1996
		JP 2005199079 A	28-07-2005
		US 5464650 A	07-11-1995
		US 5837008 A	17-11-1998
		US 5679400 A	21-10-1997
US 2004034409 A1	19-02-2004	AT 336272 T	15-09-2006
		DE 10237572 A1	26-02-2004
		EP 1389471 A1	18-02-2004
		JP 2004097804 A	02-04-2004
DE 10357747 A1	05-01-2005	CN 1805763 A	19-07-2006
US 5916584 A	29-06-1999	WO 9612466 A1	02-05-1996
		CA 2202510 A1	02-05-1996
		EP 0788340 A1	13-08-1997
		NZ 294546 A	29-04-1999
		ZA 9509041 A	17-07-1996
US 5518730 A	21-05-1996	AU 665844 B2	18-01-1996
		AU 4405893 A	30-12-1993
		CA 2137268 A1	09-12-1993
		DE 69332210 D1	19-09-2002
		DE 69332210 T2	24-04-2003
		EP 0746342 A1	11-12-1996
		JP 7507548 T	24-08-1995
		WO 9324154 A1	09-12-1993
US 2002165601 A1	07-11-2002	WO 02089707 A1	14-11-2002

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2006/025937	30.06.2006	30.06.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61L31/14 A61F2/82

Applicant
ADVANCED CARDIOVASCULAR SYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d	see form PCT/ISA/210	Peris Antoli, Berta

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/025937

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2006/025937

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 1, 3, 4, 6-14,16-20, 22-26, 28-30, 32-32 (in part); 10, 15 (industrial applicability)

because:

☒ the said international application, or the said claims Nos. 10, 15 (industrial applicability) relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 1, 3, 4, 6-14,16-20, 22-26, 28-30, 32-32 (in part)

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☒ complied with

   ☐ not complied with for the following reasons:

4. Consequently, this report has been established in respect of the following parts of the International application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7, 9-25, 30-32
	No:	Claims	1-6, 8, 26-29
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-32
Industrial applicability (IA)	Yes:	Claims	1-9, 11-14, 26-32
	No:	Claims	

2. Citations and explanations

see **separate sheet**

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

D1: WO 98/56312 A (SCIMED LIFE SYSTEMS INC [US]) 17 December 1998 (1998-12-17)
D2: US 2003/153972 A1 (HELMUS MICHAEL [US]) 14 August 2003 (2003-08-14)
D3: EP-A2-1 362 603 (TERUMO CORP [JP]) 19 November 2003 (2003-11-19)
D4: US-B1-6 867 248 (MARTIN DAVID P [US] ET AL) 15 March 2005 (2005-03-15)
D5: US-A-5 624 411 (TUCH RONALD J [US]) 29 April 1997 (1997-04-29)
D6: US 2004/034409 A1 (HEUBLEIN BERND [DE] ET AL) 19 February 2004 (2004-02-19)
D7: DE 103 57 747 A1 (MNEMOSCIENCE GMBH [DE]) 5 January 2005 (2005-01-05)
D8: US-A-5 916 584 (O'DONOGHUE MICHAEL F [AU] ET AL) 29 June 1999 (1999-06-29)
D9: US-A-5 518 730 (FUISZ RICHARD C [US]) 21 May 1996 (1996-05-21)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The present independent claims 1, 4, 14 and 20 relate to an extremely large number of possible implantable medical devices. Similarly, independent claims 26 and 30 relate to methods for coating an extremely large number of possible substrates. Support and disclosure in the sense of Article 6 and 5 PCT is to be found, if any, only for stents [see e.g. dependent claims 2, 5, 15, 21, 27 and 31]. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search of independent claims 1, 4, 14, 20, 26 and 30 (PCT Guidelines 9.19 and 9.23). The search of independent claims 1, 4, 14, 20, 26 and 30 was restricted to those medical devices/substrates specified in the dependent claims 2, 5, 15, 21, 27 and 31.

2. According to Rule 66.1(e) PCT, no international preliminary examination will be carried out in respect of the subject matter which is not covered by the search report.

2.1 Thus, **for the purpose of this report**, independent **claims 1, 4, 14, 20, 26 and 30** have **been read as if restricted to**

- **(i) stents** (claims 1, 4 and 14),
- **(ii) methods for fabricating a stent** (claim 20) and
- **(iii) methods for coating a stent substrate** with a bioabsorbable coating region (claims 26 and 30).

The dependent **claims 3, 6-13, 16-19, 22-25, 28-29 and 32 have been read accordingly**.

3. Present independent claims 26 and 30 do not meet the requirements of Art. 5 and 6 PCT for the reasons indicated below (see point 10).

3.1 Thus, **for the purpose of this report**, independent **claims 26 and 30** have **been further read as if** the "bioabsorbable coating" were a **"bioabsorbable polymer coating"**.

The dependent **claims 27-29 and 31-32 have been read accordingly**.

4. **Claims 10 and 25**, as far as they relate to the "formation of pores" *in vivo*, can be regarded as relating to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item IV

Lack of unity of invention

5. The international preliminary examining authority is of the opinion that the present application does not comply with the requirements of unity of invention as set forth in Rule 13.1 PCT, for the following reasons:

5.1 The problem posed in the present application (see p.4, l.13-20) was to provide means for controlling the erosion of biodegradable stents to maintain structural stability.

5.2 As proposed in the claims, said problem can be solved by several means, namely

(1) with a device (stent) having a bioabsorbable polymeric substrate coated with a bioabsorbable polymeric coating having a lower average erosion rate than the substrate [**claims 1-3**];

(2) with a device (stent) having a bioabsorbable substrate coated with a bioabsorbable polymeric pore-forming coating [**claims 4-13**]; and a method for preparing such a device [**claims 20-25 (in part)**];

(3) with a device (stent) having a bioabsorbable substrate coated with a bioabsorbable polymeric porous coating [**claims 14-19**]; as well as a method for preparing such a device [**claims 20-25 (in part)**];

(4) by coating a bioabsorbable (stent) substrate with a bioabsorbable (polymeric) coating and by further controlling a thickness of the coating [**claims 26-29**]; and

(5) by coating a bioabsorbable (stent) substrate with a bioabsorbable (polymeric) coating and by further controlling a degree of crystallinity of the coating [**claims 30-32**].

5.3 The common concept linking the aforementioned solutions (1) to (5) is the use of "*a bioabsorbable polymeric coating for coating a bioabsorbable stent or stent substrate*". Said concept is not new, because stents comprising a bioabsorbable substrate coated with a bioabsorbable coating are already known from D1 to D3 (see points 7.1 to 7.3 below).

5.4 Thus the devices and methods specified in items (1) to (5) of point 5.2 above are considered to relate to different inventions or groups of invention which are not linked by a single inventive concept, contrary to the requirements of Rule 13.1 PCT.

6. Although the claimed subject matter does not comply with the requirements of unity of invention, this authority has chosen, according to rule 68.1 PCT, not to invite the applicant to restrict the claims or to pay additional fees, in particular because due to the objections raised in point 1 above, the search of claims 1-31 has been restricted to devices/methods according to claims 2, 5, 15, 21, 27 and 31.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Novelty

7. **Claims 1-6, 8** and **26-29** do not meet the requirements of Art. 33(2) PCT because their subject matter is not new (see below).

7.1 **D1** (see e.g. claims 1-5 and 14 in conjunction with p.2, l.20-24; passage bridging pp.2-3; and p.3, l.13-19) discloses biodegradable (i.e. bioabsorbable) stent comprising

(i) an inner core formed of a first biodegradable polymeric layer having a preselected biodegradation or lifetime, and

(ii) a second outer biodegradable polymeric layer (preferably composed of a surface erodible polymer), said outer layer exhibiting a longer degradation period than the first layer and providing protection of the inner layer material.

D1 also indicates that a drug may be optionally incorporated in at least the first or the second polymer layer. D1 (see p.6, l.15 to p.7, l.5) discloses the preparation of one stent of said kind, indicating that a drug can be incorporated in the outer layer.

D1 (see p.6, l.7-14) also teaches that once a material for the outer layer has been selected, the thickness of the outer layer can be varied to control the degradation time of the stent.

Thus, **D1** destroys the novelty of the subject matter of present **claims 1-3 and 26-29**.

7.2 **D2** (see e.g. §[0009], [0013], [0016], [0036]-[0038], [0046], [0047], [0057], [0069] and [0070]) discloses a biodegradable (i.e. bioabsorbable) stent, comprising

(i) an inner biodegradable polymeric core (composed of bulk eroding or surface eroding material), coated with

(ii) a biodegradable polymeric material, preferably a hydrophobic surface eroding material (-which will erode more slowly than the bulk eroding material-), which acts as a diffusion barrier that prevents body fluids from contacting the core material, thereby controlling the rate at which the core becomes more flexible (i.e. degrades and loses mechanical stability).

D2 also teaches that the thickness of the coating material can be selected to extend or shorten (i.e. to control) the erosion of the material and hence to extend or shorten

the time period prior penetration of body fluids into the core. D2 further teaches the possible incorporation of a drug into the core or the coating materials.

Thus, **D2** also destroys the novelty of the subject matter of present **claims 1-3 and 26-29**.

7.3 **D3** (see e.g. claims 1, 3, 7-11 in conjunction with §[0028], [0031], [0032] and [0066]-[0071]) discloses a biodegradable (i.e. bioabsorbable) drug-loaded stent comprising

(i) a main stent body (substrate) formed of biodegradable polymer;

(ii) a layer of a biologically active substance provided on the surface of the stent body; and

(iii) a layer of a biodegradable polymer which completely covers the layer of active substance, said polymer layer comprising a water-soluble pore-forming substance dispersed therein.

D3 teaches that upon contact with body fluids, the water-soluble pore-forming substance elutes from the outer polymeric layer, thereby forming pores which permit contact of the body fluids with the underlying drug-layer, and the drug releases from the stent. By subsequent gradual degradation of the outer pore-forming layer, the active substance is eventually completely released from to the body. Furthermore, by adequately selecting the composition and molecular weight of the biodegradable polymer, the drug-release can be designed for controlled release periods e.g. of 30-60 days.

The teachings of **D3** prejudice the novelty of the subject matter of present **claims 4, 6 and 10**.

Inventive step

8. **Claims 1-32** do not meet the requirements of Art. 33(3) PCT for the reasons set out below.

8.1 **D1 and D2** (see points 7.1 and 7.2 above) teach bioabsorbable stents comprising an inner polymeric core (or substrate) and an outer polymeric coating, wherein the outer coating is said to exhibit a longer degradation rate than the core material thereby providing protection of the inner core (see **D1**) or to act as a diffusion barrier that

prevents body fluids from contacting the core material, thereby controlling the rate at which the core becomes more flexible (i.e. degrades and loses mechanical stability) (see **D2**). D1 and D2 also teach that the thickness of the outer coating can be varied to control the degradation time of the stent (see **D1**) or to control the penetration rate of body fluids into the core (see **D2**) [--which will invariably affect the degradation rate of te core--].

8.1, Therefore, **D1 and D2** clearly teach the use of bioabsorbable polymeric stent coatings for retarding, and hence for controlling, the degradation of the underlying core material and hence for retarding/controlling the degradation of the whole coated stent. Due to said teachings, **D1 and D2 represent the closest prior art** for the claimed subject matter.

8.2 The subject matter of present **claims 1-3 and 26-29** is already anticipated by the teachings of D1 and D2 (see points 7.1 and 7.2 above). Hence, no inventive step can be recognised for said subject matter.

8.3 The subject matter of present claims 4-25 and 30-32 essentially differs from that of D1-D2 in the physical form of bioabsorbable coating used to coat the bioabsorbable substrate, namely

(i) a pore-forming coating or a porous coating, in the case of claims 4-25, or
(ii) a coating having a degree of crystallinity controlled, in the case of claims 30-32.

8.4 So, starting from D1 and D2, as closest prior art, the objective **problem to be solved** by the subject matter of present claims 4-25 and 30-32 can be regarded as to provide alternative bioabsorbable coating means for controlling the degradation rate of bioabsorbable stents.

8.5 The possible use of bioabsorbable polymeric coatings for altering the degradation of medical devices (e.g. stents) coated with such coatings is not only known from D1/D2 (see above) but also from D4.

Indeed, **D4** (see e.g. c.4, l.5-29 in conjunction with c.9, l. 23-35; c.9, l.56 to c.10, l.15 and c.14, l. 29-33) discloses biocompatible biodegradable (i.e. bioabsorbable) polyhydroxy-alkanoate (PHA) polymer compounds, the degradation of which can be modified by different measures, e.g. by altering their chemical composition, their molecular weight, their

porosity (e.g. by means of hydrophilic pore-forming substances), etc. It further teaches the possible use of said polymeric compounds for coating medical devices in order to improve their biocompatibility, mechanical properties and for tailoring their degradation or controlled release profiles.

8.6 In view of the aforementioned knowledge, those skilled in the art would readily recognise that any bioabsorbable polymeric coating suitable for application onto a bioabsorbable stent substrate, and having a prolonged biodegradation or bioerosion rate, would be suited for retarding, and hence for controlling, the degradation of the underlying substrate, and consequently for retarding or controlling the degradation of the coated stent as a whole.

8.7 As indicated above (see point 7.3), **D3** teaches the use of bioabsorbable pore-forming polymer coatings for retarding or prolonging the release of active drugs from a drug-loaded stent, in which the drug is positioned as a layer overlaying the stent body but underlying the pore-forming coating.

8.8 Similarly, **D5** (see e.g. claims 1, 3-5 and 19-23 in conjunction with c.3, l.15-16 and l.27-34; as well as c.7, l.5-15, and l.27-61) teaches a drug-loaded stent comprising

(i) an expandable body stent;

(ii) a therapeutic substance provided as a layer on the surface of the stent body; and

(iii) a porous biodegradable polymer coating overlying the therapeutic substance layer, said porous layer being formed either by spraying of the polymer or by phase inversion precipitation;

D5 further indicates that the release rate of the drug from the stent is controlled by the porous coating which rather reduces than increases the drug elution rate, presumably due to its decreased susceptibility to cracking as the stent undergoes deformation during handling and implantation.

8.9 In view of the teachings of D3 and D5, in combination with those of D1-D2, optionally also with those of D4, it would have been obvious for those skilled in the art to use pore-forming or porous biodegradable polymer coatings with a reasonable expectation of success that they would solve the problem posed.

Thus, no inventive step can be recognised for the subject matter of independent **claims 4, 14 and 20** or their dependent **claims 5-13, 15-19 and 21-25**. [With regard to the dependent claims, it is to be noted that the use of biodegradable or bioerodible metallic stent cores or substrates, instead of biodegradable polymeric substrates, in biodegradable coated stents, would be an obvious measure for the skilled person, since said kind of stents are already known from the state of the art; see e.g. **D6** (claims 1-6) or **D7** (claims 1-3, and 6). It is further to be noted that the preparation or pore-forming or porous coatings is well known to the skilled artisan; see e.g. **D3** (claims 8-1), **D4** (paragraph bridging cc.9-10) or **D5** (claims 19-21 and c.7, l.27-62)].

8.10 As acknowledged in the application (see p.28, l.3-4), it is known that the diffusion rate of a fluid through a polymer decreases as the degree of crystallinity increases; see e.g. **D8** (c.8, l.50-56). It s also known that the degradation of a polymer (including bioabsorbable polymers) can be retarded by increasing its crystallinity; see e.g. **D8** (c.3, l.39-48 and c.7, l.51 to c.8, l.61) or **D9** (paragraph bridging cc.2-3).
Combining said knowledge with the teachings of D1 and/or D2, and optionally with those of D6 and/or D7 (see point 8.9 above) , no inventive step can be recognised for the subject matter of present **claims 30-32**.

Industrial applicability:

9. **Claims 1-9, 11-14 and 16-32** satisfy the criterion set forth in Art. 33(4) PCT because their subject matter is susceptible of industrial application.

9.1 As far as **claims 10 and 15** relate to the "formation of pores" *in vivo*, (--which can be considered as a method of treatment of the human or animal body--), no unified criteria exist in the PCT Contracting States For the assessment of said claims on the question of whether they are industrially applicable. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VIII

Certain observations on the international application

10. The independent **claims 26 and 30** do not meet the requirements of Art. 5 and 6 PCT, because the claimed subject matter, namely, the *bioabsorbable coating region (--assumedly a polymeric coating--) to be applied to the bioabsorbable substrate* is merely defined by the results to be achieved; i.e. as "being configured to reduce, inhibit or delay the erosion of the substrate and by further controlling a thickness (see claim 26) or a degree of crystallinity (see claim 30) of the coating to allow a specified amount of erosion of the substrate during a selected period of time".
Said functional definition of the bioabsorbable coating region solely refers to technical effects to be achieved and in no way provide information as to the technical features required for achieving the desired effects. Said functional definitions hence puts undue burden on the skilled person seeking to establish the scope of the claims and willing to carry out the invention over the whole claimed field.